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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,173	04/14/2000	Norihisa Ooe	2185-0424-SP	8838

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Birch Stewart Kolasch & Birch LLP
P O Box 747
Falls Church, VA 22040-0747

EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,173

Applicant(s)

OOE ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 29, 2004 has been entered. No amendments were made to the claims.

Claims 1-9 and 11-17 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed June 10, 2003, that is not addressed in this action has been withdrawn.

Information Disclosure Statement

The information disclosure statement filed February 9, 2004 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action. It is noted that the reference for US 5,650,283 has been lined through because it has already been cited on a form PTO-892, therefore it is a duplicate reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9 and 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "securely maintaining" or "securely maintained" in claims 1, 2, 9, 14 and 17 (and their dependent claims) are relative terms which render the claim indefinite. The term "securely maintained" is defined in the specification as meaning "that an introduced DNA does not fall out from a cell in some days, for example, about 5 to 7 days" (see for example page 12 of the instant specification). This is indefinite because it is not clear how long a DNA must remain in a cell in order for it to be considered "securely maintained;" although the definition cites an example of "securely maintaining," this example does not describe the metes and bounds of the term because it is unclear what other examples might also fit within the metes and bounds of "securely maintained." For instance, it is unclear if a single day is also an example of being "securely maintained." In view of the definition of the term "securely maintained" in the specification, it is clear that the metes and bounds of the claim are not defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield (as cited in the previous Office Actions; US Patent 5,650,283) in view of

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Waldman (as cited in the previous Office Actions; *Analyt. Biochem.* **258**: 216-222, 1998). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradfield in view of Waldman (as applied to claims 1, 3-9, 11 and 13-17), in further view of Kushner (as cited in the previous Office Actions; US Patent 6,117,638). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Applicant cites specific locations in the specification where specific constructs are discussed. These constructs are indicated as pGL3-TATAEREx5-BSD and pGL3-tk-EREx5-BSD. See for example page 3 of Applicant's remarks.
2. Applicant asserts that none of the references cited teach that their cells would show a higher sensitivity in detection of ligand-responsive transcription activity, and therefore would not have been motivated to combine the teachings of the references in order to obtain the cells (and therefore their use in the claimed methods).

Applicant's arguments have been considered but are not found persuasive for the following reasons:

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1. The specific constructs set forth above in Applicant's first argument are not present in any of the claims as limitations. Therefore, an argument by Applicant that these constructs can confer to the claimed invention any patentable distinction over the prior art is moot, because these limitations are not in the claims. However, as established in the previous Office Actions, Bradfield in view of Waldman, and then again in view of Kushner does teach the entire invention as claimed. Bradfield describes the use of mammalian cells expressing the Ah receptor and the ARNT receptor in assays to detect agonists of the transcriptional activities of the receptor (see column 23, lines 30-33 and lines 41-46) by measuring the activity of a reporter gene that has been operatively linked to a transcriptional response element for the Ah receptor (see column 2, lines 56-62). The Ah receptor is maintained in the cell on a plasmid also containing a selectable marker, while the reporter gene is present on a second plasmid, but in the same molecule with a second selectable marker (see Figure 11). Furthermore, Bradfield explicitly indicates that the Ah receptor and ARNT *or* the chimeric Ah receptor can be expressed in mammalian cells (see column 23, lines 44-46). This must be interpreted to mean the full-length Ah receptor was used in the assay described by Bradfield. Waldman then teaches a method of securing DNA within a cell for up to 20 generations of growth. Motivation to combine these teachings is provided by Waldman which indicates their method is "fast, economical and of general utility" (see abstract, last sentence). These references can be further combined with Kushner, who teaches a method for screening compounds in cells (including mammalian) that both activate (agonist) and block (antagonist) the stimulation of transcription of genes, some of which are regulated by hormone receptors, using a minimal promoter region comprised of a TATA box (see especially column 14, lines 39-49 and 57-64 and column 15, lines 32-41 and 60-63). Motivation to combine these

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teachings comes from the desire to identify compounds that could attenuate (antagonize) the affects of hormone receptor transcription response hyperactivation, which is prevalent with respect to the estrogen receptor and its role in breast cancer formation (see Kushner column15, line 40-41). These teachings, by encompassing all of the limitations set forth in the claims, make the instant claims obvious despite the specific constructs presented in Applicant's remarks, which are not limitations in the claims.

2. In response to Applicant's argument that 'none of the references cited teach that their cells would show a higher sensitivity in detection of ligand-responsive transcription activity, and therefore [the skilled artisan] would not have been motivated to combine the teachings of the references in order to obtain the cells,' the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). As set forth in the previous Office Actions, there was substantial reason to combine the teachings of Bradfield and Waldman (i.e., because the method of transformation provided by Waldman is "fast, economical and of general utility"), and then the teachings of Bradfield and Waldman, in further view of Kushner. The argument that Applicant has found a particular motivation that is not provided in the references cited does not preclude the references being combined under different motivation.

In conclusion, Applicant has not provided a substantial argument as to why the combined teachings of Bradfield, Waldman and Kushner do not make the instantly claimed invention obvious. The references teach all of the claimed limitations, and the Office has provided adequate motivation to combine each of the references, despite Applicant's assertion that a

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particular motivation cannot be found in the references. As a result, the claimed invention is still found to be obvious, and remains rejected under 35 USC 103(a).

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



**JAMES KETTER
PRIMARY EXAMINER**